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March 10, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Showcase International, Inc. located at 853 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past 30 days marketed a dietary supplement bearing the following additional statement(s) on the label and/or in the labeling:

<u>Enzygen®</u>: [is] a natural aid to proper digestion and nutrition. [It] provides a blend of vital enzymes that are necessary for the assimilation, absorption and digestion of foods. Enzygen stimulates the release of nutrients from your food which are critical for cellular regeneration. [It] breaks down fats, carbohydrates and proteins. [It] promotes proper digestion. [It] converts food into useful nutrients. [It] stimulates the release of essential nutrients from your food which are critical for cell regeneration and proper digestion. [It] helps maintain proper stomach acidity.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Showcase International, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed

Sincerely,

Deborah Shur Trinker Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure

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